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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,900

Applicant(s)

HARRIS ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 37-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 37-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Objections

Claims 42 and 65-95 are objected to because of the following informalities:

In claims 42 and 65-95, the parent application PCT/US99/16070 does support the subject matter claimed herein to a three-cup prosthesis of a shell, acetabular cup, and a femur cup where the cup sizes are in the range of 35 mm to 70 mm. It appears that the Applicant is trying to claim the features of two embodiments as if they are of the same embodiment (Figure 1's embodiment combined with Figure 8's embodiment). There is no suggestion from the specification that this can be done. It also suggests that the present application is a continuation-in-part of the parent application PCT/US99/16070. For this reason, these claims lack proper antecedent basis from the specification.

The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter of claims 42 and 65-95. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The parent application PCT/US99/16070 does not support the subject matter claimed herein to a three-cup prosthesis of a shell, acetabular cup, and a femur cup. For this reason, these claims lack proper antecedent basis from the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 39, 40, 42, 43, 45-65 and 67-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly claimed range of about 35 mm to 70 mm does not have original support when it is combined with femur cup thicknesses of over about 5mm. Rather, when the large diameter head is used the cups have thicknesses in the 1mm to 5 mm range; see page 10, lines 1-27 and page 15, lines 8-22.

Regarding claims 81-88, the range of ball accommodation of up to a diameter of 70 mm lacks original support because the specification appears to only support a range of ball size up to 46 mm because the socket size is limited to 59 by the disclosure; see page 17, lines 4-23 of the specification. It appears that the application is mixing mutually exclusive species to attempt to broaden the invention from what was originally disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 38, 41, 42, 90 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et al (US 5,549,700) in view of McKellop et al (US

6,165,220) and Townley (US 6,096,084). Graham discloses shell (13) which corresponds to the acetabular cup as claimed and cup(s) (18) and/or (20) which can be 2.0 or 3.5 mm thick which correspond to the femur cup as claimed; see Figure 3 and column 8, lines 12-36. However, Graham fails to disclose a "crosslinked" UHMWPE cup material as claimed or the head diameter of greater than 35 mm as claimed. McKellop, however, teaches that it was known to crosslink similar prosthetic cups in order to improve wear resistance; see the front page thereof as well as column 2, lines 12-18. Townley teaches that it was known to make femur heads in the size range of 38 to 55 mm; see column 7, lines 32-42. Hence, it is the Examiner's position that it would have been obvious to crosslink the internal surface of the Graham UHMWPE cup in order to improve wear resistance. Furthermore, it would have been obvious to make the cup(s) 18 and/or 20 capable of receiving heads of 35 mm or greater so that the larger size femur head implants or natural femurs of larger individuals could be used with Graham.

With regard to claim 42, the acetabular cup as claimed is met by cup (18) of Graham, and the femur cup as claimed is met by combination of all segments of (20) of Graham.

Claims 1, 37-41, 43-59, 61-62, 64-89, 91, 92, 94, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townley et al (US 6,096,084) in view of McKellop et al (US 6,165,220).

Townley meets the claim language where the acetabular cup as claimed is met by the porous cobalt chromium layer and/or the cement layer (301) of Townley, and the

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femur cup as claimed is met by the cup (300) of Townley. The cup thickness is obviously greater than 1 mm by inspection of the drawings and comparing the thickness of the cup the diameter of the ball; see Figures 1-8 and 8 as well as column 4, line 24 to column 6, line 35 and column 7, lines 54-58. However, Townley fails to disclose a "crosslinked" UHMWPE cup material as claimed. McKellop, however, teaches that it was known to crosslink similar prosthetic cups in order to improve wear resistance; see the front page thereof as well as column 2, lines 12-18. Hence, it is the Examiner's position that it would have been obvious to crosslink the internal surface of the Townley UHMWPE cup in order to improve wear resistance.

With regard to claims 41 and 42, the shell as claimed is met by the porous cobalt-chrome layer.

With regard to claims 40, 47, and 69, Townley discloses in Figure 8 a cup having a thickness about $3\text{mm}/22\text{mm}=0.14$ or 14% of the thickness of the head. Since the head can vary from 38 mm to 55 mm, the shell thickness can vary from about 5.3 mm to about 7.7 mm. Therefore, Townley fails to disclose a shell thickness of more than about 7.7 mm. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the cup thickness because Applicants have not disclosed that the cup thickness provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because UHMWPE is sufficiently strong for its intended purpose at a

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thickness of 5 mm. Therefore, it would have been an obvious matter of design choice to modify Townley to obtain the invention as specified in the claims.

With regard to claims 50, 75, and 79, Townley discloses a ball having a diameter between 38 mm and 55 mm. Therefore, Townley fails to disclose the ball diameters claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the ball diameter because Applicants have not disclosed that the 70 mm to 90 mm diameter ball provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would fit larger patients and give a larger wear area therefor. Therefore, it would have been an obvious matter of design choice to modify Townley to obtain the invention as specified in the claims.

With regard to claims 54, 55, 70, 71, the Examiner asserts that these claimed parameters are inherently present in the material disclosed by Townley as modified by McKellop because it is the same crosslinked material claimed and disclosed.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Townley and McKellop as applied to claim 1 above, and further in view of DeCarlo, Jr. (US 4,524,467). Townley fails to disclose the varying degrees of movement as claimed. However, DeCarlo discloses that greater degrees of freedom with partial hemispheric portions were known to the art; see the abstract and figures. Hence, it is the Examiner's position that it would have been obvious to put partial hemispheric portions in the Townley device for the same reasons that DeCarlo does the same.

Claims 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townley and McKellop as applied to claim 1 above, and further in view of Teinturier (US 4,385,405). Townley fails to disclose an ovoid head as claimed. However, Teinturier teaches that it was known to make contact surfaces for ovoid heads; see column 4, lines 18-26. Therefore, it would have been obvious to make ovoid heads in the Townley device in order to correspond to the shape of the cup of Teinturier.

Response to Arguments

Applicant's arguments filed July 6, 2004 have been fully considered but they are not persuasive or were rendered moot.

In response to the argument that there is antecedent basis for the three-cup system, the Examiner does not agree and has added further explanation of this position in the objection. Applicant is referred to the objection of the claims and specification set forth earlier.

The Examiner has withdrawn the 35 USC 112, second paragraph rejections of claims 81-88 because of the open-ended ranges. However, the amendment introduced new matter in the claims.

Applicants argued that there was no motivation to combine McKellop with Graham. In response, the Examiner asserts that the motivation is provided by McKellop in the abstract for crosslinking the polyethylene.

Applicants argue that some of the applied references do not teach a 35 or greater ball size. In response to applicant's arguments against the references

individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Response to Amendment

The declaration filed under 37 CFR 1.132 filed July 6, 2004 is insufficient to overcome the rejection of the claim based upon the applied prior art as set forth in the last Office action because:

(1) The objective evidence and inventor's arguments are not supported by actual proof. Rather, the objective evidence, in the form of prior art citations, merely suggested that some in the art had evidence that a larger head size, along with other factors, attributed to higher wear rates. Exhibit 1 suggested that larger head sizes and younger more active patients resulted in higher wear rate, but no actual proof was provided. Exhibit 2 concluded that there was a difference in wear between 28 mm and 32 mm diameter surfaces but that the differences "were not statistically significant." Again, no actual evidence was provided and the claimed range was not tested. Exhibit 4 provided no actual data but suggested that higher wear rates were found when comparing 32 mm diameter surfaces with 28 mm and 26 mm surfaces. Exhibit 6 was primarily concerned with the effects of synovial fluids on wear. Exhibit 7 pertained to cementless fixation and not to wear. Similarly Exhibits 9 and 10 were concerned with cementless fixation and osteolysis and not to wear characteristics.

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(2). The exhibits did not provide actual proof because they did not compare the closest prior art to the presently claimed invention in a side-by-side test. Rather, the evidence concerned devices outside of the claimed ranges.

(3). The declaration was executed by an inventor of the present application, and thus, the declarant had a vested interest in the application.

(4). Consequently, the Examiner concluded that the declaration suggested that there was a trend in the art to smaller diameter surfaces, but the Examiner concluded that this did not suggest unobviousness to one of ordinary skill to the disadvantage of using larger diameter surfaces because of prior art references such as Townley.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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